Alternative Microbiological Methods:  
A Workshop on Current Status and Future Directions of Compendial Standards  
March 16–17, 2015 
USP Headquarters, Rockville, Maryland

Preliminary Agenda  
(As of January 28, 2015 – Subject to Change)

Monday, March 16, 2014 (Day 1)

8:00 a.m. Registration and Coffee

9:00 a.m. Welcome, Opening Remarks, and Workshop Overview  
James Akers, Ph.D., Chair, USP Microbiology Expert Committee

9:30 a.m. Plenary Session I: Alternate Methods  
Moderator: TBA
   a. Current USP Perspectives  
      James Akers, Ph.D., Chair, USP Microbiology Expert Committee
   b. Current FDA Perspectives  
      Speaker TBA

10:10 a.m. Discussion / Q&A

10:30 a.m. Plenary Session II: Status of Current Chapters  
Moderator: TBD
This session will highlight current status of the chapters on Alternative Microbiological Methods in USP, European, and Japanese Pharmacopoeias
   a. New Draft <1223.1>: Alternate Procedures to Antibiotic Microbial Assays  
      Speaker TBA

10:50 a.m. Break

11:20 a.m. Plenary Session II: Status of Current Chapters (Continued)  
   b. <1223> Revisions – USP Representative  
      Speaker TBA
   c. EP 5.1.6. Alternative Methods for Control of Microbiological Quality:  
      Current Status of Revisions  
      Stephen Wicks, Ph.D., European Directorate for the Quality of Medicines (EDQM), France

12:00 p.m. Discussion / Q&A

12:45 p.m. Lunch

1:45 p.m. Plenary Session III: Equivalence Approaches  
Speakers representing the USP and EP will present on the proposed equivalence approaches to alternative microbiological methods.  
Moderator: TBD
   a. Equivalence Determination  
      Anthony Cundell, Ph.D., Vice Chair, USP Microbiology Expert Committee
   b. Statistical Tools for Validation of Alternative Microbiological Methods  
      Edwin van den Heuvel, Ph.D., Professor of Medical Statistics, de Eindhoven University of Technology (TU/e) in Eindhoven, Netherlands
3:05 p.m.  Break
3:30 p.m.  Discussion / Q&A
5:00 p.m.  Reception in Corridor of Volunteers
6:00 p.m.  Adjourn for the day

**Tuesday, March 17, 2014 (Day 2)**

8:00 a.m.  Registration and Coffee
9:00 a.m.  Overview of Days Topics  
*Speaker TBA*

**Plenary Session IV: Modern Microbiological Methods**  
*Moderator: TBD*

Speakers representing the USP General Chapters–Microbiology Expert Committee, Japanese Pharmacopoeia (JP), Industry, and U.S. Food and Drug Administration (FDA) will present on current perspectives on Modern Microbiological Methods (MMM)

- **a.** Current USP Perspectives on a Compendial MMM Sterility Test  
  *James Akers, Ph.D., Chair, USP Microbiology Expert Committee*
- **b.** Current FDA perspectives on Sterility Tests FDA/ CBER  
  *Speaker TBA*
- **c.** Industry Perspective  
  *David Roesti, Ph.D., Novartis, Switzerland*

10:30 a.m.  Break
11:00 a.m.  **Plenary Session IV: Modern Microbiological Methods (Continued)**

- **d.** Current JP Perspectives  
  *Masao Nasu, Ph.D., University of Osaka, Japan*
- **e.** Current Status of Proposed USP Chapter <71.1>  
  *Anthony Cundell, Ph.D., Vice Chair, USP Microbiology Expert Committee*

12:00 p.m.  Lunch
1:00 p.m.  Round Table Discussion / Q&A
2:30 p.m.  Summary of Discussions: What Was Said, What Was Heard, Next Steps  
*Moderator: Radhakrishna Tirumalai, Ph.D., USP*

3:00 p.m.  Break
3:30 p.m.  **Final Remarks / Conclusions**  
*James Akers, Ph.D., Chair, USP Microbiology Expert Committee*

4:00 p.m.  Workshop Adjourns